UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JAZMINE HARRIS, individually and on behalf of all others similar situated,	)	
Plaintiff,	)	
	)	No. 20 C 4355
v.	)	
	)	Judge Sara L. Ellis
TOPCO ASSOCIATES, LLC,	)	
Defendant.	)	

OPINION AND ORDER

Plaintiff Jazmine Harris purchased Defendant Topco Associates, LLC ("Topco) Infants' Pain & Fever Acetaminophen (the "Infants' Product") for her baby under the assumption that the product was specifically formulated for infants, only to learn that it has the same ingredient and concentration of acetaminophen contained in Topco's Children's Pain & Fever Acetaminophen (the "Children's Product"). Harris now bring this putative class action alleging that Topco designed its products to mislead a parent into purchasing the Infants' Product at a higher cost. Harris' amended complaint alleges violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 P.S. § 201-1 *et seq.*, and unjust enrichment. Topco moves to dismiss the amended complaint, arguing that the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, expressly preempts Harris' claims. Alternatively, Topco argues that Harris has not adequately pleaded the elements of her state law claims. Because

Harris seeks to change the labeling on the Infants' Product, the FDCA preempts her state law claims.

BACKGROUND[1]

I. The Parties

Topco is incorporated in the State of Delaware, with its principal place of business located in Elk Grove Village, Illinois. It operates as a strategic sourcing company that provides procurement, quality assurance, packaging, and other services for its food industry member-owners and customers. Its brands include Top Care®, which offers products such as over-the-counter ("OTC") drugs and first-aid, including a brand of pain reliever and fever reducer under the "TopCare®" label for the Infants' and Children's Products.

Harris resides in Pittsburgh, Pennsylvania and has purchased the Infants' Products for approximately one year. She first purchased the Infants' Product for her then one-year old child at Giant Eagle, a Topco member-owner store located in Pittsburgh, Pennsylvania.

II. The Infants' and Children's' Products

Acetaminophen is an active ingredient in OTC drugs and prescription medications to alleviate pain and fever. Prior to 2011, liquid acetaminophen was available for infants with a concentration of 80 mg per 1 mL compared to liquid acetaminophen with a concentration of 160 mg per 5 mL for children. But between 2000 and 2009, the Food and Drug Administration (the "FDA") received reports of twenty children dying from acetaminophen toxicity and potentially

[1] The Court takes the facts in the background section from Harris' amended complaint and presumes them to be true for the purpose of resolving the Topco's motion to dismiss. *See Phillips v. Prudential Ins. Co. of Am.*, 714 F.3d 1017, 1019–20 (7th Cir. 2013). Although the Court normally cannot consider extrinsic evidence without converting a motion to dismiss into one for summary judgment, *Jackson v. Curry*, 888 F.3d 259, 263 (7th Cir. 2018), the Court may consider "documents that are central to the complaint and are referred to in it" in ruling on a motion to dismiss, *Williamson v. Curran*, 714 F.3d 432, 436 (7th Cir. 2013). The Court "may also take judicial notice of matters of public record." *Orgone Cap. III, LLC v. Daubenspeck*, 912 F.3d 1039, 1043–44 (7th Cir. 2019).

three deaths stemming from the different concentrations of the two pediatric medicines. To prevent confusion over the concentrations, as well as additional accidental acetaminophen toxicity, in 2011, manufacturers voluntarily changed the liquid acetaminophen marketed for infants to be the same concentration as the liquid acetaminophen marketed for children, 160 mg per 5 mL. The FDA recommended having one concentration of OTC pediatric liquid acetaminophen as different concentrations in products could cause confusion among caregivers that could lead to unintentional overdoses in pediatric patients. Thus, since 2011, the only variance in acetaminophen products marketed for infants and children is the price point at which it is sold and the plastic dosing instrument included with the product.

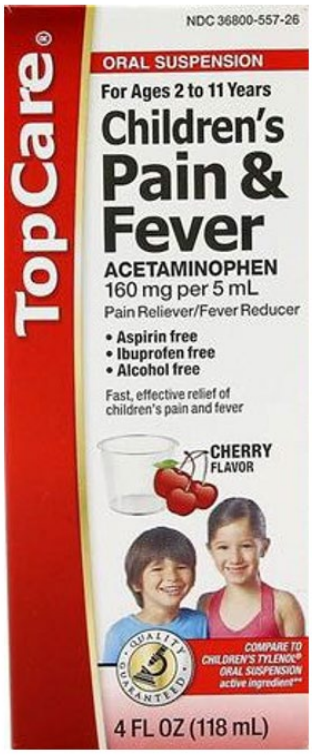
Topco's Infants' Product and Children's Product have the same concentration of acetaminophen. The Infants' Product retails for $4.99 for two ounces of medicine. The front of the box of the Infants' Product displays an infant crawling and includes the following statements, among others: "Infants'" (in bold, black lettering) and "Compare to Infants' Tylenol® Oral Suspension active ingredient." Doc. 26 ¶ 24. Further, the principal display panel states that this product should be used only with the enclosed syringe. And the instruction section of the label notes "[use] only enclosed syringe specifically designed for use with this product. Do not use

any other dosing device." *Id.* ¶ 24. An image of the front of the Infants' Product is reproduced below:

Id.

Looking at the Children's Product, the front of the box displays two older children. The outer packaging also includes the following statements: "Children's" (in bold, black lettering); "Ages 2 to 11 Years"; and "Compare to Children's Tylenol® Oral Suspension active ingredient." *Id.* ¶ 26. The label also includes instructions on how to use the product, stating that it should only be used with the enclosed dosing cup specifically designed for use with the product, and that no other dosing device should be used. Compared to the Infants' Product, the Children's

Product retails for $4.99 for four ounces of medicine. An image of the front of the Children's Product is reproduced below:



Id.

III. Harris' Purchase of the Infant Product

Harris first purchased the Infants' Product for her then one-year old infant in Pittsburgh, Pennsylvania at a Giant Eagle, a Topco member-owner store, where someone directed her to the infant section in the store's OTC medicine section. Harris bought the Infants' Product because she saw that it was for infants, and, based on the packaging, marketing, and labeling, believed it to be specifically formulated for infants. She believed that the Infants' Product differed from the Children's Product, and had she known that the Infants' Product was not specially formulated for infants, she would not have purchased it. Harris would not have been willing to pay the higher cost for the Infants' Product, or to purchase the Infants' Product whatsoever, had Topco not put

the word "Infants" so prominently on the front label or omitted that both the Infants' Product and the Children's Product were identically formulated.

LEGAL STANDARD

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint, not its merits. Fed. R. Civ. P. 12(b)(6); *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990). In considering a Rule 12(b)(6) motion, the Court accepts as true all well-pleaded facts in the plaintiff's complaint and draws all reasonable inferences from those facts in the plaintiff's favor. *Kubiak v. City of Chicago*, 810 F.3d 476, 480–81 (7th Cir. 2016). To survive a Rule 12(b)(6) motion, the complaint must assert a facially plausible claim and provide fair notice to the defendant of the claim's basis. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Adams v. City of Indianapolis*, 742 F.3d 720, 728–29 (7th Cir. 2014). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

ANALYSIS

Topco first argues that § 379r(a) of the FDCA expressly preempts Harris' state law claims because they seek to enforce new labeling requirements. Harris responds that Topco has not identified a federal requirement that could differ from the claims at issue and so FDCA preemption does not apply.

The FDCA does not provide a private right of action; therefore, Harris may only seek relief pursuant to related state-law causes of action. *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). "The latter right, however, is tightly circumscribed by the FDCA's express preemption of state-law theories that impose requirements 'not identical' to its own

requirements." *Benson v. Fannie May Confections Brands, Inc.*, 944 F.3d 639, 645 (7th Cir. 2019). For the purposes of preemption, the FDA has said that:

> "Not identical to". . . means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or (ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

21 C.F.R. § 100.1(c)(4). The term "requirements" "sweeps broadly." *Turek v. Gen. Mills, Inc.*, 754 F. Supp. 2d 956, 958 (N.D. Ill. 2010) (quoting *Cipollone v. Liggett Grp. Inc.*, 505 U.S. 504, 521 (1992)), *aff'd*, 662 F.3d 423. States can impose requirements that are identical to those imposed by the FDCA, but not different from or more burdensome than those requirements. *Chi. Faucet Shoppe, Inc. v. Nestle Waters N. Am., Inc.*, 24 F. Supp. 3d 750, 758 (N.D. Ill. 2014). Thus, to avoid preemption, a state law claim related to misleading labeling must allege a violation of the FDCA.[2] *Turek*, 662 F.3d at 426.

Harris first argues that her claims are consistent with, not different from, the FDCA requirements because they are premised on the theory that the Infants' Product labels are false and misleading, and the FDCA specifically prohibits "labeling [that] is false or misleading." 21 U.S.C. § 352(a). Harris misses the points of preemption, however, as her claims are based on the labeling of the products themselves, not on a legal theory. *See Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 376–77 (S.D.N.Y. 2014) ("This argument rests on a mistaken premise. . . . With respect to the labeling of OTC drugs, the whole point of section 379r is that it is not up to private litigants—or judges—to decide what is 'false or misleading.'") *But see Burchfield v.*

[2] Although preemption is an affirmative defense, the amended complaint reveals that preemption applies to the claims at hand here and so the Court may address it under Rule 12(b)(6). *Cf. Benson*, 944 F.3d at 645.

Prestige Consumer HealthCare, Inc., No. 2:20-CV-10717, Doc. 44 at 12–13 (C.D. Cal. Apr. 16, 2021) (misleading labeling claim not preempted where, if proven, the claims "would simply require Defendant to truthfully state [the nature of its product] or not sell its products" (quoting *Fagan v. Neutrogena Corp.*, No. 5:13-CV-01316-SVW-OP, 2014 WL 92255, at *1 (C.D. Cal. Jan. 8, 2014))). And, looking at the amended complaint, the crux of Harris' claims would require Topco to label its products in a particular way, as she seeks to impose "clear disclosures that there is no pharmacological distinction between 'Infant's Product' and 'Children's Product.'" Doc. 26 ¶ 57.

The FDA regulates Topco's Infants' and Children's Products pursuant to the 1988 Tentative Final Monograph (the "TFM") that governs the marketing of OTC drugs. *See* FDA, *Internal Analgesic, Antipyretic, & Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph*, 53 Fed. Reg. 46204 (Nov. 16, 1988). The TFM includes requirements for disclosures and mandatory labeling of acetaminophen products. Harris argues, however, that, due to its tentative nature, the TFM does not have the force of law and no controlling final monograph exists that concerns acetaminophen products. *See Emley v. Wal-Mart Stores, Inc.*, No. 1:17-CV-2350-WTL-TAB, 2019 WL 2642842, at *5 (S.D. Ind. June 27, 2019) ("By its very terms, the tentative final monograph does not have the force of law; therefore, the Defendants cannot be in violation of federal law by failing to comply with it."); *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 144 F. Supp. 3d 699, 731 (E.D. Pa. 2015) ("Furthermore, Extra Strength Tylenol was and still is regulated by the Tentative Final Monograph (TFM) which is only a proposed rule" (citations omitted)). But the cases Harris cites were decided before the enactment of the CARES Act in 2020. And the CARES Act has deemed the TFM to have the force of law as a final monograph, providing that tentative

monographs for Category I drugs, including acetaminophen, are final administrative orders. *See* 21 U.S.C. § 355h(b)(8)(A) ("A . . . tentative final monograph described in subparagraph (B) shall be deemed to be a final administrative order under this subsection[.]"). Because the Court finds the TFM sets forth federal labeling requirements for acetaminophen products based on the CARES Act, the Court proceeds to consider whether the amended complaint states a violation of those requirements so as to allow Harris to avoid FDCA preemption.

Harris' state law claims assert that, in distributing, marketing, advertising, and labeling the Infants' Products, Topco failed to make material disclosures, including a disclosure notifying consumers that Infants' Products are the same as the Children's Products. As stated above, the equitable relief she seeks is an injunction to provide "clear disclosures that there is no pharmacological distinction between 'Infant's Product' and 'Children's Product' and that the two products can be used interchangeably in a manner that is safe to infants and children alike." Doc. 26 ¶ 57. As Topco points out, the TFM does not bar the labeling of acetaminophen products appropriate for infants as "Infant" products. Indeed, the TFM provides that "products that are clearly identified for use in children, e.g., infant drops, children's aspirin or acetaminophen tablets, do not have to be labeled with a statement in the warnings or in the directions specifying that they are for children under twelve years." 53 Fed. Reg. at 46,219. All that the TFM requires is that labeling of the product contains on the display panel either the word children's and the trade name of the product, or the trade name followed by "for Children." *Id.*

At oral argument, Harris pointed to two new, recent decisions out of the Central District of California, *Burchfield v. Prestige Consumer HealthCare, Inc.*, No. 2:20-CV-10717, Doc. 44 (C.D. Cal. Apr. 16, 2021), and *McFall v. Perrigo Co.*, No. 2:20-cv-07752, Doc. 70 (C.D. Cal. Apr. 15, 2021), as instructive here because, in both cases, the court declined to find plaintiffs'

similar claims about the labeling of infants' and children's acetaminophen preempted.[3] But the arguments with respect to preemption in both cases, most notably in *McFall*, are different than those raised here. In *McFall*, the court determined that the plaintiffs' claims were not identical to the requirements of the FDCA nor to the TFM because the infant's product was labeled as being suitable for ages two to three years old and the TFM requires products for children ages two to twelve years old to bear a children's identifier. *McFall*, No. 2:20-cv-07752, Doc. 70 at *13. Here, Topco is only arguing that, in accordance with the TFM, the labeling states that the Infants' Product is simply safe for infants. And Harris is asking Topco to state more than that; namely, that the Infants' Product is the same product as the Children's Product. Simply put, Harris is asking more than what the TFM requires. Because the TFM does not require any specific disclaimers concerning infant products nor the interchangeability of the two products at issue, Harris' claims are preempted because she seeks to impose additional obligations on Topco not imposed by the TFM.[4] *See Turek*, 662 F.3d at 427 ("The disclaimers that the plaintiff wants added to the labeling of the defendants' inulin-containing chewy bars are not identical to the labeling requirements imposed on such products by federal law, and so they are barred. The information required by federal law does not include disclosing that the fiber in the product includes inulin or that a product containing inulin produces fewer health benefits than a product that contains only 'natural' fiber, or that inulin from chicory root should not be consumed by pregnant or lactating women."); *see also Curran v. Bayer Healthcare LLC*, No. 17 C 7930, No.

[3] Also at oral argument, Harris' counsel raised an argument that the placement of the dosage amount on the Infants' Product label does not comply with FDA requirements. But Harris' entire complaint is not about where things are placed on the label but rather that the label fails to make clear that the Infants' Product and the Children's Product are the same product, thus where the dosage amount is located on the packaging would not affect that claim. To the extent that Harris wants to make such a claim, she can amend the complaint to address this argument.

[4] Because the Court concludes that the FDCA preempts Harris' claims, it does not address Topco's alternative arguments concerning the viability of her claims.

17 C 7930, 2018 WL 2431981, at *3 (N.D. Ill. May 30, 2018) ("To the extent [the plaintiff] wishes to add to or change the requirements, his claims are preempted"); *Chi. Faucet Shoppe, Inc.*, 24 F. Supp. 3d at 759 ("[S]tate law cannot be used to fill what private litigants perceive to be gaps in the regulatory requirements imposed by federal law.").

CONCLUSION

For the foregoing reasons, the Court grants Topco's motion to dismiss the amended complaint [30] without prejudice.

Dated: May 11, 2021

SARA L. ELLIS
United States District Judge